Children's Mercy HOSPITALS & CLINICS

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December 23, 1999

Docket Number 97N-484S
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville MD 20852

Dear Sir or Madam:

I wish to comment on the FDA proposed rule entitled "Suitability Determination for Donor of Human Cellular and Tissue-Based Products".

I object to the FDA's proposed definition of *minimally manipulated* because the term *minimally* is vague and open to subjective, ever changing definitions. The term *manipulated* is also vague and open to subjective interpretation. These proposed terms should be eliminated as they add nothing to the proposed rule and have nothing to do with donor suitability.

I object to the FDA's proposed definition of *homologous use* because *homologous* is vague and open to subjective interpretation. The term *use* infringes on the practice of medicine. How a doctor decides to use a device should not affect how it is regulated. The entire term should be eliminated. There is no threat to the public health with these tissues to warrant this type of term being used or distinction being made. Implementation of this term and its subsequent regulation may restrict availability as tissue banks try to comply with new FDA rules.

I use allograft bone tissue in my practice and do not wish its supply to be curtailed through excessive and unnecessary government regulation. I see no added benefit to having these definitions in the proposed rule.

My patients benefit from my use of allograft bone to treat a wide variety of conditions, some of which have no man-made material labeled alternative.

Thank you for the opportunity to comment on this proposed rule.

Sincerely,

Thomas L. Schmidt, MD
Director, Pediatric Orthopaedic Surgery

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